

10/734,640

MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

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Substitute for form 1449B/PTO

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

Date Submitted: October 18, 2004

(use as many sheets as necessary)

## Complete if Known

Application Number	10/734,640
Filing Date	12/15/2003
First Named Inventor	Bruno DE LIGNIERES
Group Art Unit	1614
Examiner Name	Not yet assigned
Attorney Docket Number	029488-0111

Sheet

1

of

4

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
W	A1	4,919,937		Pierre Mauvais-Jarvis	4/24/1990	

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
In French	A2	J. BARRAT et al., "Effet <i>in vivo</i> de l'administration locale de progestérone sur l'activité mitotique des galactophores humains", J. Gynecol. Obstet. Biol. Reprod. 19: 269-274 1990.	
W	A3	Bronaugh & Maibach, "Percutaneous Absorption Drugs-Cosmetics-Mechanisms-Methodology", Marcel Dekker Inc., New York, 1999.	
W	A4	Philip CARTHEW et al., "Cumulative exposure to tamoxifen: DNA adducts and liver cancer in the rat", Arch Toxicol (2001) 75: 375-380.	
W	A5	Gerard CHETRITTE et al., "Effect of Promegestone, Tamoxifen, 4-Hydroxytamoxifen and ICI 164,384 on the Oestrone Sulphatase Activity of Human Breast Cancer Cells", Anticancer Research 13: 931-934 (1993).	
W	A6	Eric C. DIETZE et al., "Tamoxifen but Not 4-Hydroxytamoxifen Initiates Apoptosis in p53(-) Normal Human Mammary Epithelial Cells by Inducing Mitochondrial Depolarization", The Journal of Biological Chemistry Vol. 276, No. 7, Issue of February 16, 2001, pp. 5384-5394.	

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		Filing Date	12/15/2003
		First Named Inventor	Bruno DE LIGNIERES
		Group Art Unit	1614
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		Attorney Docket Number	029488-0111

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CR	A7	Ian S. FENTIMAN, "Tamoxifen and Mastalgia an Emerging Indication", Drugs, Vol. 32, No. 6, December 1986, pp. 477-480.	
CR	A8	I.S. FENTIMAN et al., "Dosage and duration of tamoxifen treatment for mastalgia: a controlled trial", BR. J. SURG. September 1988, Vol. 75, No. 9, pp. 845-846.	
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CR	A11	IBIS investigators, "First results from the International Breast Cancer Intervention Study (IBIS-I): a randomised prevention trial", The Lancet, Vol. 360, September 14, 2002, pp. 817-824.	
CR	A12	V. Craig JORDAN et al., "Metabolites of tamoxifen in animals and man: identification, pharmacology, and significance", Breast Cancer Research and Treatment, 2, pp. 123-138.	
CR	A13	George G.J.M. KUIPER et al., "Comparison of the Ligand Binding Specificity and Transcript Tissue Distribution of Estrogen Receptors $\alpha$ and $\beta$ ", Endocrinology, Vol. 138, No. 3, 1997, pp. 863-870.	
	A14	Frédérique KUTTENN et al., "MÉDECINE ET THÉRAPEUTIQUE", C.R. Acad. Sc. Paris, , Série III, No. 12, 1985, 300:457-461.	
CR	A15	Catherine MALET et al., "Tamoxifen and Hydroxytamoxifen Isomers versus Estradiol Effects on Normal Human Breast Cells in Culture", Cancer Research, Vol. 48, No. 24, December 15, 1988, pp. 7193-7199.	

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*Christophe Lateral*

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		Filing Date	12/15/2003
		First Named Inventor	Bruno DE LIGNIERES
		Group Art Unit	1614
		Examiner Name	Not yet assigned
Sheet	3	of	4
		Attorney Docket Number	029488-0111

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ll	A16	Pierre MAUVAIS-JARVIS et al., "trans-4-Hydroxytamoxifen Concentration and Metabolism after Local Percutaneous Administration to Human Breast", Cancer Research, Vol. 46, March 1986, pp. 1521-1525.	
ll	A17	Henri PUJOL et al., "Phase I Study of percutaneous 4-hydroxy-tamoxifen with analyses of 4-hydroxy-tamoxifen concentrations in breast cancer and normal breast tissue", Cancer Chemother. Pharmacol., 36:493-498 (1995).	
ll	A18	David W. ROBERTSON et al., "Synthesis of the E and Z Isomers of the Antiestrogen Tamoxifen and Its Metabolite, Hydroxytamoxifen, in Tritium-Labeled Form", J. Org. Chem., 1982, Vol. 47, No. 12, pp. 2387-2393.	
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ll	A20	Fabrice SAUVEZ et al., "Cutaneously applied 4-hydroxytamoxifen is not carcinogenic in female rats", Carcinogenesis Vol. 20, No. 5, pp. 843-850 1999.	
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ll	A22	Deborah N. ADER PhD, et al., "Prevalence and impact of cyclic mastalgia in a United States clinic-based sample", Am. J. Obstet. Gynecol., Vol. 177, No. 1, pp. 126-132, July 1997.	
ll	A23	M.R. CALLANTINE PhD. et al., "Micronized 17 $\beta$ -Estradiol for Oral Estrogen Therapy in Menopausal Women", Obstetrics & Gynecology Vol. 46, No. 1, July 1975, pp. 37-41.	
ll	A24	A. GORINS et al., "A FRENCH DOUBLE-BLIND CROSSOVER STUDY (DANAZOL VERSUS PLACEBO) IN THE TREATMENT OF SEVERE FIBROCYSTIC BREAST DISEASE", Eur. J. Gynaec. Oncol. Vol. 2, 1984, pp. 85-89.	
ll	A25	S.J. Graham PhD, "Changes in Fibroglandular Volume and Water Content of Breast Tissue During the Menstrual Cycle Observed by MR Imaging at 1.5 T", JMRI, Vol. 5, No. 6, November/December 1995, pp. 695-701.	

Examiner Signature		Date Considered	2/23/07
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Substitute for form 1449B/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  Date Submitted: October 18, 2004  (use as many sheets as necessary)		Application Number	10/734,640
		Filing Date	12/15/2003
		First Named Inventor	Bruno DE LIGNIERES
		Group Art Unit	1614
		Examiner Name	Not yet assigned
Sheet	4	of	4
		Attorney Docket Number	029488-0111

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
le	A26	R.E. MANSEL et al., "A Double Blind Trial of the Prolactin Inhibitor Bromocriptine in Painful Benign Breast Disease", Br. J. Surg. Vol. 65, (1978), pp. 724-727.	
le	A27	Catherine S. MURPHY et al., "Structure-Function Relationships of Hydroxylated Metabolites of Tamoxifen that Control the Proliferation of Estrogen-Responsive T47D Breast Cancer Cells In Vitro", Molecular Pharmacology, 38, pp. 737-743, (1990).	
le	A28	Lawrence H. BLOCK, PhD, "Epidermal and Transdermal Drug Delivery", Medicated Topicals, Chapter 44, Remington: The Science and Practice of Pharmacy, Alfonso R. Gennaro, Lippincott Williams and Wilkins, 2000, pp. 836-858.	
le	A29	M. SAMBROOK et al., "Ultrasonic Doppler Study of the Hormonal Response of Blood Flow in the Normal Human Breast", Ultrasound In Med. & Biol. Vol. 13, No. 3, pp. 121-129 (1987).	

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10/734,640

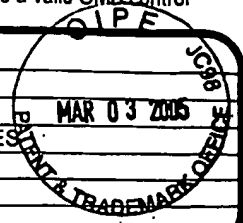
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Substitute for form 1449B/PTO				Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  Date Submitted: March 3, 2005  <i>(use as many sheets as necessary)</i>				Application Number	10/734,640
				Filing Date	12/15/2003
				First Named Inventor	Bruno DE LIGNIERES
				Group Art Unit	1614
				Examiner Name	Unassigned
Sheet	1	of	1	Attorney Docket Number	029488-0111



U.S. PATENT DOCUMENTS						
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		B1	DE 38 36 862 A1		Gunther Clemens et al.	5/3/1990		

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Date Submitted: June 2, 2005			Filing Date	12/15/2003
(use as many sheets as necessary)			First Named Inventor	Bruno DE LIGNIERES
			Group Art Unit	1614
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WR	C1	4 919 937		Mauvais-Jarvis et al.	4/24/1990	
WR	C2	2003/0153543 A1		Masato TANABE et al.	8/14/2003	
WR	C3	5 189 212		University of Georgia Research Foundation	2/23/1993	

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
WR	C4		EP 0 792 640 A2		PFIZER INC.	9/3/1997	
WR	C5		EP 1 106 179 A2		PFIZER INC.	6/13/2001	
WR	C6		WO 02/36129 A2		Alfred SCHMIDT et al.	5/10/2002	
WR	C7		WO 02/03969 A2		HEXAL AG	1/17/2002	
WR	C8		EP 1 177 787 A2		Pfizer Products Inc.	2/6/2002	

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WR	C9	International Search Report of PCT/EP03/15028		
—	C10	P. MAUVAIS-JARVIS, "Le traitement hormonal des mastopathies benignes", Bull Cancer (1991) 78, 365-371.		
WR	C11	I.S. FENTIMAN et al., "Dosage and duration of tamoxifen treatment for mastalgia: a controlled trial", Br. J. Surg. 1988, Vol. 75, September, 845-846.		
WR	C12	Pierre MAUVAIS-JARVIS et al., "trans-4-Hydroxytamoxifen concentration and Metabolism after Local percutaneous Administration to Human Breast", Cancer Research 46, 1521-1525, March 1986.		
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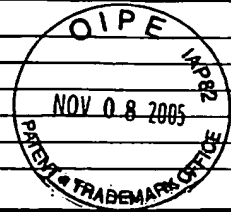
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Sheet	1	of	1		



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DL	D1	2002/0115676 A1		David B. MACLEAN	8/22/2002	
	D2	2003/0065017 A1		PFIZER INC.	4/3/2003	
	D3	2003/0087885 A1		Valerie MASINI-ETEVE et al.	5/8/2003	
	D4	6,503,894 B1		Unimed Pharmaceuticals Inc. et al.	1/7/2003	

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DL	D5		WO 2004/110420 A1		LABORATORIES BESINS INTERNATIONAL et al.	12/23/2004	

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DL	D6	Lawrence N. PARKER et al., "Treatment of Gynecomastia with Tamoxifen: A Double Blind Crossover Study", Metabolism, Vol. 35, No. 8, 1986: pp. 705-708.	

Examiner Signature	<i>Christy A. Lee</i>	Date Considered	2/23/2007
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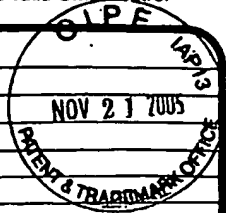
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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> Date Submitted: November 21, 2005 (use as many sheets as necessary)			<b>Complete if Known</b> Application Number 10/734,640 Filing Date 12/15/2003 First Named Inventor Bruno DE LIGNIERES Group Art Unit 1617 Examiner Name Jennifer M. Kim Attorney Docket Number 029488-0111		
Sheet	1	of	1		



U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			

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lh	E1	BRISSON, J., et al., "Tamoxifen and Mammographic Breast Densities, Cancer Epidemiology, Biomarkers & Prevention, Vol. 9, pp. 911-915 (2000).		
lh	E2	"High Breast Density a Risk Factor", pp. 1-4, <a href="http://www.breastcancer.org/research_genetics_091902_pf.html">http://www.breastcancer.org/research_genetics_091902_pf.html</a> (8/11/05)		

Examiner Signature	<i>[Signature]</i>	Date Considered	2/23/07
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Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> Date Submitted: February 13, 2006 (Use as many sheets as necessary)		<b>Complete if Known</b>	
Application Number		10/734,640	
Filing Date		12/15/2003	
First Named Inventor		Bruno DE LIGNIERES	
Group Art Unit		1617	
Examiner Name		Jennifer M. Kim	
Attorney Docket Number		029488-0111	

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			

U.S. PATENT APPLICATION DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Application Document		Name of Patentee or Applicant of Cited Document	Filing Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Serial Number	Kind Code <sup>2</sup> (if known)			

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
	F1	WO	2004/054557 A2		LABORATOIRES BESINS INTERNATIONAL	7/1/2004	
	F2	WO	2004/054558 A2		LABORATOIRES BESINS INTERNATIONAL	7/1/2004	

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Substitute for form 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	
Date Submitted: August 28, 2008		10/734,640	
(use as many sheets as necessary)		Filing Date	
1		12/15/2003	
of		First Named Inventor	
1		Bruno DE LIGNIERES	
TRADEMARK OFFICE		Group Art Unit	
		1617	
		Examiner Name	
		Jennifer M. Kim	
		Attorney Docket Number	
		029488-0111	

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
JK	G1	2004/0138314	A1	BUA	7/15/2004	

## FOREIGN PATENT DOCUMENTS

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
W	G2	EP	1 579 857	A1	LABORATOIRES BESINS INTERNATIONAL	9/28/2005		
W	G3	EP	1 579 856	A1	LABORATOIRES BESINS INTERNATIONAL	9/28/2005		

## NON PATENT LITERATURE DOCUMENTS

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Examiner Signature	<i>Chet Saleh</i>	Date Considered	2/23/2007
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